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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,536	01/03/2007	Tim Hitchman	564462012600	9324

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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,536	HITCHMAN ET AL.	
	Examiner	Art Unit	
	GANAPATHIRAMA RAGHU	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *3,5,10 and 266* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/15/06; 01/03/07; 09/09/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-42, 45, 47,106,126,128,151,167, 197 and 259-272.

Continuation of Disposition of Claims: Claims rejected are 1,2,4,6,7,10,11,21-25,27,31,34,36-38,40-42,45,47,106,126,128,151,167,197,259-265 and 267-272.

Detailed Action

Claims 1-7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-42, 45, 47, 106, 126, 128, 151, 167, 197 and 259-272 are pending in this application for examination and are now under consideration.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 08/15/2006, 01/03/2007 and 09/09/2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the IDS is considered and initialed by the examiner.

Priority

Acknowledgment is made of applicants' claim for priority under 35 U.S.C. 119(e), this application is a 371 PCT/US04/25932, filed on 08/11/2004 which claims benefit of the Provisional application 60/494,472 filed on 08/11/2003.

Objections to Abstract

The Abstract of the disclosure is objected to because, Abstract should be on a separate sheet of paper. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim10 is objected to, due to the following informalities:

Claim 10 as written is grammatically awkward; examiner suggests inserting "of" after "oxidation" in line 2 of the claim.

Claim Rejections: 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide of SEQ ID NO: 24 having laccase activity, vectors, isolated host cells comprising the polynucleotide and methods for making and using said polypeptide, does not reasonably provide enablement for any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272 are so broad as to encompass any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides and encoded polypeptides broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a polynucleotide determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence and the respective codons in its polynucleotide, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the encoded proteins' structure relates to its function. However, in this case the disclosure is limited to an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide of SEQ ID NO: 24 having laccase activity, vectors, isolated host cells comprising the polynucleotide and methods for making and using said polypeptide. It would require undue experimentation of the skilled artisan to make and use the claimed polynucleotides and encoding polypeptides that are having

at least 90%-95% nucleic acid sequence identity with the nucleic acid sequence of SEQ ID NO: 23 or a portion thereof and said polynucleotides encoding a polypeptide having laccase and peroxidase activities. The specification is limited to teaching the use of a polynucleotide sequence of SEQ ID NO: 23 encoding a polypeptide having laccase and peroxidase activities, but provides no guidance with regard to the making of variants and mutants or with regard to other uses. In view of the great breadth of the claims, amount of experimentation required to make and use the claimed polynucleotides and encoded polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (for example, see Whisstock et al., Prediction of protein function from protein sequence and structure. Q Rev Biophys. 2003, Aug. 36 (3): 307-340. Review), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make and use the full scope of the polynucleotides and polypeptides encompassed by these claims.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272 as written are directed to random variant and mutant polypeptides having laccase and peroxidase activities and encoded by random mutants and variants of a polynucleotide comprising a nucleotide sequence of SEQ ID NO: 23 i.e., any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271). The guidance provided by the applicants is limited and especially to an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide of SEQ ID NO: 24 having laccase activity, vectors, isolated host cells comprising the polynucleotide and methods for making and using said polypeptide. However, polynucleotides having 90%-95% sequence identity to the nucleotide sequence of SEQ ID NO: 23, said polynucleotides encoding random variant and mutant polypeptides having laccase and peroxidase activities would clearly constitute **undue** experimentation. Furthermore, there is paucity of information in prior art that teaches laccase structures defining the catalytic domains, crystal structures and 3D model of a laccase and additionally having peroxidase activity. Therefore, enough guidance is not presented to the skilled artisan that enables the skilled artisan to identify amino acid residues that are amenable to changes and to identify variant structures of SEQ ID NO: 23 and encoding polypeptide with the

associated laccase and peroxidase function. Therefore, polynucleotides having 90%-95% sequence identity to the nucleotide sequence of SEQ ID NO: 23, said polynucleotides encoding random variant and mutant polypeptides having laccase and peroxidase activities, method of making and method of using said encoded polypeptides would clearly constitute **undue** experimentation (see scientific support below).

Guo et al., (PNAS, 2004, Vol. 101 (25): 9205-9210) teach that the percentage of random single-substitution mutations, which inactivate a protein, using a protein 3-methyladenine DNA glycosylase as a model, is 34% and that this number is consistent with other studies in other proteins (p 9206, paragraph 4). Guo et al., (*supra*) further show that the percentage of active mutants for multiple mutations/changes appears to be exponentially related to this by the simple formula $(0.66)^{\wedge x}$ X 100% where **x** is the number of mutations introduced (Table 1). Applying this estimate to the protein recited in the instant application, 90% sequence identity to the polynucleotide of SEQ ID NO: 23 encoding the polypeptide as claimed in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272 allows up to 177 mutations/changes within the 1767 nucleotides of the encoding polynucleotide sequence of SEQ ID NO: 23.

For argument sake, even if one assumes that 1/3 of the of the 177 nucleotide mutants/changes do not result in amino acid sequence changes, the number of likely nucleotide changes that produce amino acid changes will be still around 118 nucleotide changes within the 1767 nucleotides of the encoding polynucleotide sequence of SEQ ID NO: 23 and, thus, only $(0.66)^{\wedge 118}$ X 100% equivalent to $\mathbf{5.0 \times 10^{-20}}$ % of random mutants and encoded by a polynucleotide having 90% sequence identity to SEQ ID NO:

23 would be active. Similarly, applying this estimate to the protein recited in the instant application, $(0.66)^{\wedge 59}$ X 100% or **2.3×10^{-9} %** of mutants having 95% sequence homology to the polynucleotide sequence of SEQ ID NO: 23 would be active. While these calculations are only estimates of the actual situation, they are presented to provide a basis for understanding the examiner's decision on which claim scope would require only routine experimentation and which claim scope would reach a level which is undue. The guidance in the instant case and current techniques in the art (i.e., high throughput mutagenesis and screening techniques) would allow for finding a reasonable number of active mutants within hundred thousand inactive mutants of SEQ ID NO: 23, for example, applying this estimate to the protein recited in the instant application as in claim 3, 0.005% of mutants having 98% sequence identity to the polynucleotide sequence of SEQ ID NO: 23 would be active and this does not raise to the level of undue experimentation. But finding a few mutants within several billions to trillions or more, as in the claims to 90%-95% sequence identity to the polynucleotide sequence of SEQ ID NO: 23 would not be possible. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed (guided mutants). Such guidance has **not** been provided in the instant specification.

It is also noted that the art teaches several examples of how even small changes in structure can lead to changes in function. For example, Witkowski et al. (Biochemistry, 1999, Vol. 38: 11643-116150) teaches that one conservative amino acid

substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Seffernick et al. (J. Bacteriol., 2001, Vol. 183 (8): 2405-2410) teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function.

The specification does not support the broad scope of the claims which encompass any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271), because the specification does not establish: (A) a rational and predictable scheme for modifying specific nucleotides in the polynucleotide sequence of SEQ ID NO: 23 encoding a polypeptide having laccase and peroxidase activities; (B) a rational and predictable scheme for modifying any nucleic acid residue or an amino acid residue in the encoded polypeptide with an expectation of obtaining the desired biological function; (C) the tertiary structure of the molecule and folding patterns that are essential for the desired biological activity and tolerance to modifications; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polynucleotides and polypeptides with an enormous number of modifications. The scope of the claim must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1975)). Without sufficient guidance, determination of polynucleotides and polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 45 (directed to a transformed cell comprising the nucleic acid of claim 1) is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because, while claim 45 is enabling for an isolated host cell transformed with the synthetic nucleic acid as claimed, does not reasonably provide enablement for transgenic multi-cellular organisms or host cells within a multi-cellular organism that have been transformed with the synthetic nucleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim.

Claim 45 is so broad as to encompass transgenic multi-cellular organisms and host cells transformed with specific nucleic acids, including cells in *vitro* culture as well as within any multi-cellular organism. The scope of the claim is not commensurate with the enablement provided by the disclosure with regard to extremely large number of

transformed organisms broadly encompassed by the claims. While methods for transforming cells *in vitro* are well known in the art, methods for successfully transforming cells within complex multi-cellular organisms are not routine and are highly unpredictable. Furthermore, methods for producing a successfully transformed cell within the multi-cellular organism are unlikely to be applicable to transformation of other types of multi-cellular organism as multi-cellular organisms vary widely. However, in this case the disclosure is limited to only host cells *in vitro*. Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the use of host cells within a multi-cellular organism for the production of polypeptide. The scope of claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA)). Without sufficient guidance, expression of genes in a particular host cell and having the desired biological characteristics is unpredictable, the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F. 2d 731, 8 USPQ 2nd 1400 (Fed. Cir., 1988). It is suggested that the applicants limit the claim to " An isolated transformed host cell ...".

Written Description

Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272, as interpreted, are directed to a genus of nucleic acids wherein said nucleic acids encompass a large number of variant polynucleotides encoding polypeptides; i.e., any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271).

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

In the instant case, there is no structure associated with functional limitations recited with regard to the members of the genus of polynucleotides encompassing a

large number of variant polynucleotides and encoding polypeptides; i.e., any isolated polynucleotide having at least 90%-95% sequence identity with an isolated polynucleotide of SEQ ID NO: 23 and encoding a polypeptide having laccase activity (as in claims 1, 2, 4, 6, 7, 10, 11, 13, 21, 22-25, 27, 31, 34, 36-38, 197, 267, 268, 269 and 272), vectors (as in claims 40-42), host cells comprising said polynucleotides (as in claims 45 and 47) and methods for making and using said polypeptide (as in claims 106, 126, 128, 151, 167, 259-265, 270 and 271).

A sufficient written description of a genus of polynucleotides may be achieved by a recitation of a representative number of polynucleotides defined by their nucleotide sequence or a recitation of structure-function correlated features common to members of the genus, which features constitute a substantial portion of the genus. While the specification in the instant application discloses the structure of an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide of SEQ ID NO: 24 having laccase activity, vectors, isolated host cells comprising the polynucleotide and methods for making and using said polypeptide and said polynucleotide (SEQ ID NO: 23) is not representative of the structure and function of all members of the claimed genus. The specification fails to disclose by any relevant, identifying characteristics or functional properties of all the members of the genus i.e., any information as to the structures associated with functions.

The genus of polynucleotides and encoding polypeptides required in the claimed invention is an extremely large structurally and functionally variable genus. While the argument can be made that the recited genus of polynucleotides is adequately

described by the disclosure of the structure of an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide having laccase activity, since one could use structural homology to isolate those polynucleotide and encoding polypeptides recited in the claims. As taught by the art, even highly structurally homologous polynucleotides and encoded polypeptides do not necessarily share the same function. For example, Witkowski et al., (Biochemistry 38:11643-11650, 1999), teaches that one conservative amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Seffernick et al., (J. Bacteriol. 183(8): 2405-2410, 2001), teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Broun et al., (Science 282:1315-1317, 1998), teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. Therefore, the claimed genera of polynucleotides include encoding polypeptides having widely variable structure and associated functions, since minor changes in structure may result in changes affecting function and no additional information correlating structure with several distinct functions has been provided.

Due to the fact that the specification only discloses an isolated polynucleotide of SEQ ID NO: 23 encoding a polypeptide having a laccase activity and the lack of description of any additional species/variants/mutants/recombinants by any relevant, identifying characteristics or properties or structure-function correlationship for the cited

distinct functions/activities, one of skill in the art would not recognize from the disclosure that applicant was in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Allowable Subject Matter/Conclusion

None of the claims are allowable.

1. Claims 1, 2, 4, 6, 7, 10, 11, 13, 21-25, 27, 31, 34, 36-38, 40-41, 45, 47, 106, 126, 128, 151, 167, 197, 259-265 and 267-272 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and enablement.

2. Claims 3, 5 and 266 are objected as they depend from rejected base claim, claim 1.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652